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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,900	02/08/2001	John C. Smith	P 277123 PHM. 70675/US	4677

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EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/778,900	SMITH, JOHN C.	
	Examiner	Art Unit	
	Juliet C Einsmann	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 3, 4, 5, 6, 7, and 19 drawn to a method for the diagnosis of a polymorphism using nucleic acid analysis, diagnosis of a disease, and treatment of a disease, classified in class 435, subclass 6

II. Claims 1, 2, 3, 4, 5, 13, and 19 drawn to a method for the diagnosis of a polymorphism using nucleic acid analysis, diagnosis of a disease, and treatment of a disease class 424, subclass 94.1.

III. Claims 8, 9, 10, 11, 12, 16, 17, and 18, drawn to isolated nucleic acids and computer readable medium having isolated nucleic acids stored thereon, classified in class 536, subclass 23.1 and class 702, subclass 19.

IV. Claims 14 and 15, drawn to a method to prepare a medicament and a pharmaceutical pack, classified in class 424, for example.

Further Restriction Requirement Applicable to All Groups

Each group detailed above reads on more than one patentably distinct group, wherein each of the distinct group is drawn to methods for the detection of separate polymorphisms, nucleic acids comprising different polymorphic variants, treatment of a patient after diagnosis using more than one polymorphism, etc. For example, group I above encompasses nine different inventions, that is, methods for detecting each of the nine different nucleic acid polymorphisms. For the elected group (of groups I-IV), applicants

must further elect single polymorphism for examination in the appropriate product or method claim. For example, if applicant elects group I, applicant should further elect one of the nucleotide polymorphisms for examination. The examiner recognizes that many of the claims recite methods in which "one or more" polymorphism is assayed or identified. This restriction requirement is based on the fact that in the presently pending claims no claim REQUIRES more than one polymorphic site. Applicant is required to elect a single polymorphic site. In the event that methods or products are set forth that require multiple sites, the combinations that include the elected site will be considered to be within the scope of the elected invention.

If applicant elects group III, applicant should elect sequences which comprise a single polymorphism, and identify the sequences (by SEQ ID NO) that are related to the elected invention.

It is noted that claims 1-5 and 19 are included in both groups I and II. Claims 1-5 and 19 will be examined with whichever group is elected.

Each polymorphic sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect on protein structure or function, these sequences themselves represent allelic variations which have different diagnostic and therapeutic implications.

Prior to allowance, non-elected subject matter will be required to be deleted from any allowable claims.

2. It is noted that at least claims 4, 5, and 6 are improperly multiply dependent. These have been included in group I because all of the claims from which they depend are in group I.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and III and inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of inventions III can each be used in separate methods from those instantly disclosed. The nucleic acids of invention III can be used in other methods, such as to express the encoded polypeptide, for nucleic acid purification assays and for aptamer assays.

4. Inventions I and II and inventions I and IV are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods with different goals, distinct method steps and requiring different reagents and different techniques. The methods of invention I are drawn to the detection of nucleic acid polymorphisms and diagnosing of diseases, and require the use of nucleic acid analysis techniques, such a DNA sequencing or nucleic acid hybridization assays for the goal of the diagnosis of disease. The methods of group II, while encompassing some of the same method steps as the methods of group I require different process steps involved in the treatment of disease. The methods of group IV are directed towards the

preparation of medicaments and would require the steps and reagents necessary to prepare the IV is not disclosed for use in the methods for diagnosing polymorphisms and diseases of group I.

5. Invention III is unrelated to group IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the groupings represents unrelated inventions because these are not disclosed for use in the particular methods provided. The nucleic acids of group II are not disclosed for use in the methods for preparing medicaments of group III.

6. The products of groups III and IV are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acids of Group III are composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The medicament of group IV is a chemical compound designed to have bioaffecting activity for the treatment of disease. Furthermore, the products of Groups III and IV can be used in materially different processes, for example, the DNA of Group III can be used in hybridization assays. The pharmaceutical pack can be used to treat disease or conditions associated with the FLT-1 gene. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups III and IV are patentably distinct from each other.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-IV, as well as the examination of each individual polymorphism, require different searches that are not coextensive, examination of

these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C Einsmann
Examiner
Art Unit 1655

September 24, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600